JUL 1 8 2001

510(k) Summary

Mesh Cage System
Surgical Dynamics™
150 Glover Avenue
Norwalk, CT 06856
USA

Product Name: Surgical Dynamics™ (SDI) Mesh Cage System

DEVICE DESCRIPTION

The SDI Mesh Cage is a hollow cylindrical tube made from commercially pure titanium (ASTM F67). The sides of the cylinder are perforated by equally spaced round holes. The cylinder is segmented: the segments are 5mm high and the grooves can be used as cutting lines. The SDI Mesh Cage is available in 6 different diameters (10mm, 12mm, 14mm, 16mm, 20mm, and 25mm) and lengths ranging from 8mm to 100mm depending on the diameter of the cage.

The endcaps are made of commercially pure titanium (ASTM F67) and snap into each end of the SDI Mesh Cage. The exterior side of the endcap features evenly spaced round spikes providing fixation. The endcap is available in round, oval, and round angled shapes depending on the diameter of the SDI Mesh Cage. It is also offered in different heights.

The SDI Mesh Cage and endcaps are implanted using a set of stainless steel instruments whose material conforms to ASTM F899. Refer to the surgical technique manual or the instrument package insert for a full description of these instruments.

INDICATIONS FOR USE

The Surgical Dynamics Mesh Cage System is a device intended to replace a vertebral body or an entire vertebra. It is for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body or vertebra due to tumor or trauma (i.e., fracture). For both corpectomy and vertebrectomy procedures, the Surgical Dynamics Mesh Cage System is intended to be used with supplemental internal spinal fixation systems. The use of bone graft with the Surgical Dynamics Mesh Cage System is optional.

TESTING

Mechanical testing was performed, including static and dynamic compression testing, static and dynamic torsion testing, and expulsion testing.

SUBSTANTIAL EQUIVALENCE*

The Surgical Dynamics™ Mesh Cage System was claimed to be substantially equivalent* to the Rezaian Spinal Fixator (K841189). Information pertaining to these devices was provided in the submission.

*Any claim of substantial equivalence is made exclusively in regard to the U.S. Food, Drug and Cosmetic Act and should not be viewed in any other light.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 8 2001

Ms. Jenny Schuck
Regulatory Affairs Associate
United States Surgical
150 Glover Avenue
Norwalk, Connecticut 06856

Re: K003709
Trade Name: Surgical Dynamics Mesh Cage System
Product Code: MQP
Regulation: 888.3060
Class: II
Dated: June 22, 2001
Received: June 25, 2001

Dear Ms. Schuck:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INTENDED USE / INDICATIONS FOR USE

510(k) Number

K003709

Device Name

Surgical Dynamics™ Mesh Cage System

Intended Use / Indications For Use

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(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X OR Over-The-Counter Use: _____
(Per 21 CFR 801.109)

Robert Chen MD for CMW

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K003709